

Remarks

This is in response to the December 21, 2010 Office Action in the above-identified patent application. This Reply is being submitted with a request for a two-month extension of time, and fee.

5 Claims 1-19, as originally filed, were pending for purposes of the instant Office Action. Claim 1 has been further amended in this Reply. The specific amendments to the claims, shown above, are discussed in more detail, below, in view of certain rejections made against the original claims. Applicants submit that no new matter is added by the above amendments to the claims.

Obviousness-type Double Patenting Rejections

10 The claims have been rejected under the judicially created obviousness-type double patenting over the following co-pending patents: US Pat. Nos. 7,318,935; 7,329,418; 7,622,137; 7,713,547; and 7,838,031. An alternative obviousness-type double patenting rejection cites the same patents in view of US Pat. No. 6,375,956, to Hermelin, et al. Applicants submit herewith Terminal Disclaimers over US Pat. Nos. 7,318,935; 7,329,418; 7,622,137; 7,713,547; and 7,838,031, to 15 obviate these rejections. Reconsideration and withdrawal of these obviousness-type double patenting rejections is respectfully requested.

Claim Rejections under 35 USC 103

20 Claims 1-19 further stand rejected under 35 USC 103(a) as being unpatentable over US 2002/0132850 to Bartholomaeus, et al., (Bartholomaeus), and further in view of US Pat. Nos. 5,756,124 to Patel (Patel) and 6,375,956 to Hermelin, et al. (Hermelin). Applicants respectfully traverse in view of the fact that none of the cited references, taken alone or in combination, teach or suggest the claimed invention.

25 The Office Action states that Bartholomaeus discloses multi-layered tablet containing two active ingredient layers separated by a non-active ingredient layer. However, Bartholomaeus is limited in its disclosure to conventional tablets and therefore have a width that exceeds their height. This is in contrast to the claimed tablet, which expressly has a height that is greater than its width. Bartholomaeus is therefore defective in its teaching of a taller-than-wide tablet, as claimed.

In addition, the separation layer in a tablet according to Bartholomaeus is intended only for separating the two active layers to avoid incompatibility when those active contact one another. The separation layer is not intended to provide a breaking layer, through which the two actives can be divided into separate dosage forms (e.g., halves). The statement at paragraph [0031] of
5 Bartholomaeus, that “[t]he invention accordingly also provides multilayer tablets that have at least one score mark that enables the tablet to be subdivided, preferably halved” refers only to conventional tablets and conventional divisions – i.e., through a score which is provided in the top or bottom layer of the tablet which allows breaking only along the vertical plane (along the height) of the tablet. Conventional scores, which cannot be formed in the side of a tablet during compression due to the embossing impeding ejection
10 of the tablet from the die, result in division of the tablet through the active layers.

By contrast, the subject taller-than-wide tablets provide, as expressly claimed, a separation mark (which can be a score, but which is non-vertically oriented) in the side of the tablet. Such separation marks according to the subject invention provide for, and guide, breaking through
15 the claimed taller-than-wide tablet so that the active segments are not broken through when dividing the tablet. Therefore, the subject tablets, which provide separation marks for dividing tablets through an *inactive* middle layer – without being divided through an active layer – are fundamentally different than tablets of Bartholomaeus, which are can be scored, but only to be divisible through the *active* layers.

It should further be recognized that a person of ordinary skill in the art would understand
20 Bartholomaeus as teaching the inactive layer of the wider-than-tall tablet to be as thin as possible, i.e., a layer having a thickness which is enough to separate the two incompatible active layers, but not so thick as to provide undue weight or size to the tablet as a whole. Overweight or oversized tablets, i.e., those containing relatively thick inactive layers, were considered undesirable in view
25 of the swallowing difficulties or other disadvantages presented to a patient.

The teaching of a separating layer which is as thin as possible was established and accepted in the art, as taught by Lieberman and Lachman. See, H.A. Lieberrman, and L. Lachman (Eds.),
30 *Pharmaceutical Dosage Forms. Vol. I*, Marcel Dekker, Inc., New York, NY (1989), 217-224 at p. 219 (copy attached). Lieberman and Lachman clearly recite that, in a multilayer tablet containing incompatible actives, e.g., an analgesic-antipyretic decongestant consisting of aspirin and phenylpropanolamine, “[a] thin layer of placebo is placed between [the active layers] to negate the

chemical incompatibility of the active ingredients" (emphasis supplied). Accordingly, applicants believe Bartholomaeus actually teaches away from the claimed invention, which specifies a taller-than wide layered tablet which includes a relatively thick middle segment.

As provided in *In re Gurley*, "[a] reference may be said to teach away when a person of ordinary skill in the art, upon reading the reference, would be ... led in a direction divergent from the path that was taken by the applicant." 27 F.3d 551, 553 (Fed. Cir. 1994). Applicants respectfully submit that increasing the thickness of the inactive layer in a multilayer tablet would clearly be divergent from the teaching of Bartholomaeus, since it was well understood in the art that an inactive separating layer was preferably disposed as a thin layer.

Applicants respectfully submit that curing the defects of Bartholomaeus would require some disclosure or, at minimum, a suggestion of, a separation mark (serving as a guide for tablet division) in the side of a taller-than-wide tablet, as claimed. The Office Action cites the Patel and Hermelin patents as secondary references in combination with Bartholomaeus. However, applicants respectfully submit that neither of these references provide disclosure of a separation mark in the side of a taller-than-wide, multilayer tablet. Therefore, both Patel and Hermelin fail to cure the defects of the primary reference of Bartholomaeus. Thus, other than the impermissible use of applicants' own disclosure as a basis for hindsight reconstruction of the claimed invention, the motivation to combine the references of Patel and Hermelin with Bartholomaeus appear to be absent.

In addition, even when combined, the cited references taken together fail to teach or suggest the claimed invention. The secondary reference of Patel is used for its description (as shown in Figs. 1 and 2) of score marks or indicia which indicate dosage of the tablet fraction. Hemerlin is cited for its indicia indicating different days for dosing and for its suggestion of color coding the tablets. However, neither of these references provides a taller-than wide tablet having a separation mark (e.g., a score) in the side of the tablet, as claimed. Therefore, it is clear that neither reference cures the defects of Bartholomaeus, as discussed above.

It should be noted that the invention as a whole, and as claimed, provides unique properties which were unavailable from tablets as described in the cited references. These unique properties of the claimed invention further provide unique advantages that were unforeseen by persons of ordinary skill in the art having access to, or knowledge of, the cited references.

The “taller-than-wide” configuration of the claimed tablets (as it sits in the compression die) lends itself to having the vertical axis as its long axis. An inactive segment between two different-colored active segments in a taller-than-wide tablet, as claimed, can advantageously be useful as a breaking segment. This provides that the area around the midline of the vertical axis is the most advantageous area for breaking the tablets in half – and through the inactive middle segment – such that no breakage occurs to the active end segments.

Because breakage will occur easiest “across” the short axis of the tablet, the claimed taller-than-wide tablet can break through a single layer, i.e., the inactive segment. Breakage in this manner allows physical separation of the active “end” segments from one another without breaking through any part of those active segments. Therefore, the active segments can remain intact even after the whole tablet is divided into two or more portions. This feature can advantageously prevent any loss of active during the breaking of the tablet. The standard wider-than-tall tablet, as known in the art, cannot provide this advantage, even if it includes an inactive segment between two active segments because the short axis is oriented “across” the layers.

Advantageously, the claimed invention, having an inactive middle segment as its breaking segment, allows the tablet to be broken so that the break is confined to that inactive segment. In such case, there is no breakage through any portion containing active substance, thus preventing loss of active ingredient from any resulting tablet portion, even when the broken edges (of the inactive segment) may chip or crumble.

The innovation arrived at for the subject taller-than-wide tablets originated from the unique motivation to provide a tablet readily breakable into precise partial doses and thereby allowing flexible dose adjustment and titration under a single prescription and a single visit to the physician. Applicants have therefore developed an entirely new compressed tablet configuration which addresses an unmet need.

Applicants maintain that the unique configurations of the subject tablets, as a whole, would NOT have been obvious to a person of ordinary skill in the pharmaceutical formulation or tableting arts because the unexpected advantages were never before achieved by or even suggested for layered compressed tablets. Therefore, it is the position of the applicant that the tablet technologies described in the cited references would not have taught or suggested the tablets as claimed in the subject application. Reconsideration and withdrawal of the obviousness rejection under 35 USC 103(a) is respectfully requested.

In view of the above amendments, and the accompanying Remarks, applicants believe that the pending claims, as amended, are in condition for allowance and respectfully request the Notice of Allowance be issued forthwith.

Applicants invite the Examiner to contact the undersigned at the address and/or phone number
5 provided below if clarification or additional information is needed on any of these matters.

Respectfully submitted,

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